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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,884	10/15/2003	Jennifer L. Harris	18062G-003211US	7551

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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,884	HARRIS ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-114* is/are pending in the application.

4a) Of the above claim(s) *91-114* is/are withdrawn from consideration.

5)☒ Claim(s) *90* is/are allowed.

6)☒ Claim(s) *84 and 87-89* is/are rejected.

7)☒ Claim(s) *85 and 86* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 21, 2006 has been entered.

2. Applicant's Terminal Disclosure over U.S. Patent 6680178 filed August 21, 2006 pursuant to 37 CFR 1.321(c) is acknowledged and entered.

3. The Art Unit Location to which your application has been assigned at the United States Patent and Trademark Office (USPTO) is changed to Art Unit 1654.

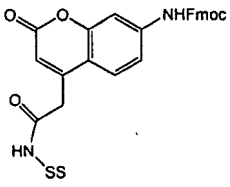
4. The assigned Examiner to your application is Julie Ha.

5. Response to Election/Restriction filed on May 30, 2007 is acknowledged. Claims 84-114 are pending in this application.

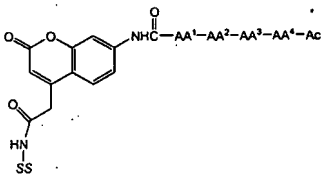
Restriction

6. Applicant's election with traverse of Group I (claims 84-90) drawn to a material having a fluorogenic moiety linked to a solid support and the species election wherein R15 is an amine protecting group in the reply filed on May 30, 2007 is acknowledged. The traversal is on the ground(s) that the subject matter recited in the claims of Groups I-VI would not place a substantially greater burden on the Examiner. The Applicants further argue that the previous Examiner handling this case was considering all of the

pending claims together in the present case. Furthermore, in the parent case (US Paten # 6680178), the Examiner examined all of the originally filed claims in a single case, all of which issued in US Patent '178. This is not found persuasive because Groups I-VI are patentably independent and distinct because the structures of the Groups are different. For example, Group I is drawn to a compound with the structure



while Group II is drawn to a library of fluorogenic peptides with the structure



. Search for would not necessarily lead to the other, since the compound of Group II comprises of amino acids that is acetylated at the C-terminal. Additionally, Group II requires that the sub-libraries be comprised of tetra- or hexa-peptides, which is not required for the composition in Groups I or V. Group V is drawn to a library of fluorogenic amino acid amides with or without solid support, and Groups III, IV and VI are drawn to methods. Further, the search for each of the inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the

consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

7. The requirement is still deemed proper and is therefore made FINAL. Claims 91-114 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or lining claims. A search was conducted on the elected species and this appears to be free of the prior art. The search was extended to the broad Markush of claim 84, and this too appears to be free of the prior art. Claims 84-90 are examined on the merits in this office action.

Objection-Minor Informalities

8. The title is objected to because the title is too long. The title is limited to 2-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.

9. The abstract of the disclosure is objected to because the abstract is too long. The Applicants are reminded that the abstract is a brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. Correction is required. See MPEP § 608.01(b) and 37 CFR 1.72(b).

Rejection-35 U.S.C. 112, 1st

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 84 and 87-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

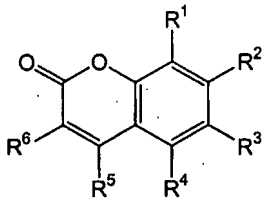
12. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

13. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

14. In the instant case, the claims are drawn to a material having a fluorogenic



moiety linked to a solid support, the material having the structure wherein R^1, R^3, R^4 and R^6 are each H, R^2 is NHR^{15}, and R^5 is $-R^{14}$-SS wherein R^{14} is --$CH_2C(O)NH$--, R^{15} is a member selected from the group consisting of amine protecting groups, -C(O)-AA and –C(O)-P. The generic statements R^{15} is a member selected from the group consisting of -C(O)-AA and –C(O)-P do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

15. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 84 is broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of amino acid or peptide or a peptide-like molecule that can form peptide bonds. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and

structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules and other synthetic peptide or peptide-like molecule that can form peptide bonds.

16. The specification is limited to the amino acid residues consisting of natural amino acids, unnatural amino acids and modified amino acids (see paragraph [0076). The specification discloses that P is a peptide sequence comprising the structure –C(O)-AA^1-AA^2-$(AA^i)_{J-2}$, and AA^1 through AA^i is an amino acid residue which is a member independently selected from the group of natural amino acid residues, unnatural amino acid residues and modified amino acid residues, J denotes the number of amino acid residues forming the peptide sequence and is a member selected from the group consisting of the numbers from 2 to 10, such that J-2 is the number of amino acid residues in the peptide sequence exclusive of an amino acid residue relevant to AA^1, and when J is greater than 2, i is a member selected from the group consisting of the numbers from 3 to 10 (see paragraph [0074]). The specification does not describe any examples of –C(O)-AA or -C(O)-P at R^{15}. Description of peptide libraries wherein P1 is fixed and having P1-P4 is not sufficient to encompass numerous other amino acids and peptides and proteins that belong to the same genus. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up

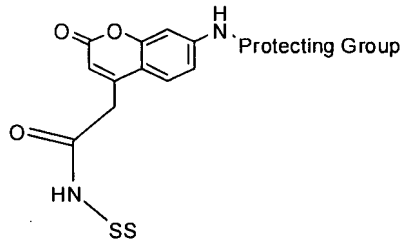
the genus. As disclosed in the specification, amino acid residues consist of natural amino acids, unnatural amino acids and modified amino acids. There are 20 naturally occurring amino acids, and there are unnatural amino acids (such as D-amino acids of the naturally occurring amino acids, beta amino acids, e-amino acids), synthetic amino acids, amino acid mimetics and modified amino acids such as methylated Phe. There are innumerable possibilities of what the single amino acid residue can encompass. With the case where in R^{15} is –C(O)-P, since the peptide can be AA^1-AA^2-$(AA^i)_{J-2}$, and AA^1 through AA^i is an amino acid residue which is a member independently selected from the group of natural amino acid residues, unnatural amino acid residues and modified amino acid residues, J denotes the number of amino acid residues forming the peptide sequence and is a member selected from the group consisting of the numbers from 2 to 10, such that J-2 is the number of amino acid residues in the peptide sequence exclusive of an amino acid residue relevant to AA^1, and when J is greater than 2, i is a member selected from the group consisting of the numbers from 3 to 10, this peptide can encompass any vast number of different peptide content. As described above, there are 20 naturally occurring amino acids, and there are unnatural amino acids (such as D-amino acids of the naturally occurring amino acids, beta amino acids, e-amino acids), synthetic amino acids, amino acid mimetics and modified amino acids such as methylated Phe. There are innumerable possibilities of what the single amino acid residue can encompass, thus, there is innumerable possibilities of peptide and different combination of amino acid residues. Thus, there is not sufficient amount of

examples provided to encompass the numerous characteristics of the whole genus claimed.

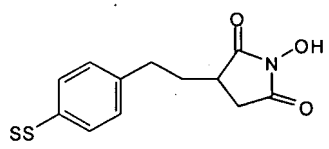
17. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Allowable Subject Matter

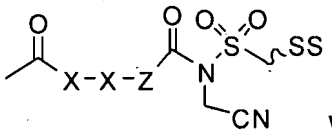
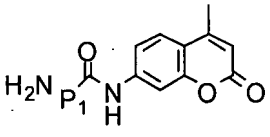
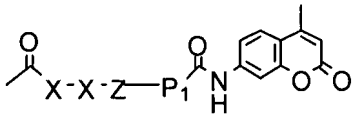
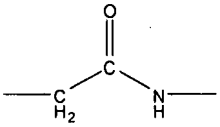
18. Claims 85-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 90 is allowable. The claims are drawn to a material having a fluorogenic moiety linked to a solid support having the structure

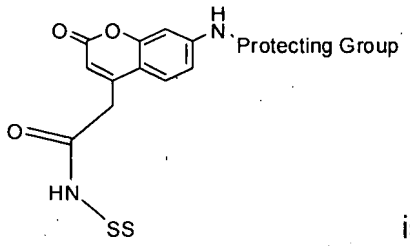


. Support bound fluorogenic materials are known in the art:



(see for example, Adamczyk et al, Bioorganic & Medicinal

Chemistry Letters, 1999, 9: 217-220). The closest art found was Backes et al (Nature Biotechnology, 2000, 187-193). Backes et al teach  with the solid support reacting with  to form  . Backes et al does not teach a solid support structure bound to the structure  on the 6th carbon of the ring structure and does not teach a amine group protected with a protecting group on the carbon at position 2 on the ring. It would not be obvious to attach a solid support from the amine group coming off of the carbon at position 6. There are other sites that can have solid support attached to, such as the NH bonded to carbon at position 2, or any other sites that has a free amine or free carbon group, as shown by Adamczyk et al above. Furthermore, solid support can be attached to the reactant compound, as shown by Backes et al above. Thus, the invention structure



is both novel and unobvious over the prior arts.

Conclusion

19. Claims 85-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims. Claims 84 and 87-89 are rejected. Claim 90 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

1/18/07
ANISH GUPTA
PRIMARY EXAMINER